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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,882	06/21/2006	Anthony Martin	15568.28	8754

22913 7590 11/13/2007

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EXAMINER	
JOYNER, KEVIN	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
11/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,882	MARTIN, ANTHONY	
	Examiner	Art Unit	
	Kevin C. Joyner	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/4/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 8 recites the limitation "in the chamber" in line 3. There is insufficient antecedent basis for this limitation in the claim. Claim 1 from which claim 8 depends comprises a main chamber and a plenum chamber. It is unclear as to which chamber the Applicant is referring to.

4. Claim 9 recites the limitation "the means" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is suggested for the Applicant to amend the claim as though it reads, "the apparatus."

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hornby (U.S. Patent No. 5,906,794) in view of McVey et al. (U.S. Publication No. 2004/0184950).

Hornby discloses an enclosure (30) for carrying out an operation under sterile conditions comprising a main chamber (11), a plenum chamber, a filter (15 and 23) separating the plenum chamber from the main chamber, a pump (16) for the plenum chamber for delivering air into the plenum chamber and then through the filter to the main chamber to create a filtered flow of air through the chamber and means for drawing gas from the enclosure via an outlet from the plenum chamber to create a flow from the main chamber through the filter decontaminating the filter and through the plenum chamber to the outlet to maintain pressure in the main and plenum chambers below atmospheric so that any leak paths result in leakage from the atmosphere into the chambers (column 1, lines 35-50; column 2, lines 26-40). Hornby does not appear to disclose that the main chamber contains a first apparatus disposed within the chamber for generating and delivering a sterilant vapour from a supply held within the chamber to be distributed throughout the chamber to sterilize the surfaces. McVey discloses an enclosure for carrying out an operation under sterile conditions comprising a main chamber as shown in Figure 1. The reference continues to disclose that the main chamber contains a first apparatus (42) disposed within the chamber in order to generate and deliver a sterilant vapour from a supply held within the chamber to be distributed throughout the chamber to sterilize the surfaces (paragraph 23). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to

include a first apparatus disposed within the main chamber in order to generate and deliver a sterilant vapour from a supply held within the chamber to be distributed throughout the chamber to sterilize the surfaces as exemplified by McVey.

Regarding claim 6, as described above with respect to claim 1 Hornby continues to disclose that the enclosure has a main chamber and a plenum chamber separated from the main chamber by a filter, the plenum chamber having a pump (16) for delivering air into the plenum chamber through the filter (15 and 23) to the main chamber to create a filtered flow of air through the chamber and the means for drawing gas from the chamber remote from the first apparatus is connected to the plenum chamber as shown in Figure 2 (column 1, lines 35-50; column 2, lines 26-40). Hornby does not appear to disclose an apparatus for producing sterilant vapour located within the main chamber and within which the operation to be carried out in the chamber is performed. McVey discloses an enclosure for carrying out an operation under sterile conditions comprising a main chamber as shown in Figure 1. The reference continues to disclose that the main chamber contains a first apparatus (42) disposed within the chamber in order to generate and deliver a sterilant vapour from a supply held within the chamber to be distributed throughout the chamber to sterilize the surfaces (paragraph 23). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a first apparatus disposed within the main chamber in order to generate and deliver a sterilant vapour from a supply held within the chamber to be distributed throughout the chamber to sterilize the surfaces as exemplified by McVey.

3. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hornby (U.S. Patent No. 5,906,794) in view of McVey et al. (U.S. Publication No. 2004/0184950) as applied to claim 1 above, and further in view of Childers (U.S. Patent No. 5,906,794).

Regarding claims 2-4, Hornby continues to disclose that the means for drawing gas from the enclosure comprises a fan (32) located in a conduit connected to an outlet from the enclosure. Hornby does not appear to disclose a means for rendering sterilant reaching the conduit ineffective to avoid release of sterilant to the atmosphere. Childers discloses an enclosure for carrying out an operation under sterile conditions comprising a main chamber and an apparatus for generating and delivering a sterilant vapor to the chamber as shown in Figure 6. The reference continues to disclose an outlet from the chamber that contains a means (20) for rendering the sterilant reaching a conduit ineffective comprising a catalytic converter that is located upstream of a fan in order to decompose the sterilant to harmless constituents comprising water and oxygen (column 5, lines 59-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Hornby to include a means for rendering the sterilant reaching a conduit ineffective comprising a catalytic converter that is located upstream of a fan in order to decompose the sterilant to harmless constituents comprising water and oxygen as exemplified by Childers.

4. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hornby (U.S. Patent No. 5,906,794) in view of McVey et al. (U.S. Publication No.

2004/0184950) and Childers (U.S. Patent No. 5,906,794) as applied to claims 3 and 4 above, and further in view of McClure (U.S. Patent No. 4,601,885).

Hornby in view of McVey and Childers is relied upon as set forth above. Regarding claim 5 and 12, Hornby in view of McVey and Childers does not appear to disclose that the conduit has selectively operable valve controlled outlets of larger and smaller capacities, the smaller capacity outlet being open during said period when the enclosure is to be maintained at a predetermined reduced pressure and the larger valve controlled outlet being opened during discharge of the sterilant atmosphere from the enclosure. McClure discloses a sterilization system for an enclosure that includes and outlet to relieve pressure from within the system (column 2, lines 15-24). The reference continues to disclose that the outlet has selectively operable valve controlled outlets of larger and smaller capacities, the smaller capacity outlet (41) is capable of being open during a period when the enclosure is to be maintained at a predetermined reduced pressure and the larger valve (38) is capable of being opened during discharge of the sterilant atmosphere from the enclosure (column 4, lines 1-35; Figure 2). McClure also discloses that the valves are utilized in order to control the pressure throughout the system. Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the outlet conduit of Hornby to include selectively operable valve controlled outlets of larger and smaller capacities, the smaller capacity outlet is capable of being open during a period when the enclosure is to be maintained at a predetermined reduced pressure and the larger valve is capable of being opened during

discharge of the sterilant atmosphere from the enclosure in order to accurately control the pressure throughout the system as exemplified by McClure.

5. Claims 7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hornby (U.S. Patent No. 5,906,794) in view of McVey et al. (U.S. Publication No. 2004/0184950) as applied to claim 6 above, and further in view of Krainiak et al. (U.S. Patent No. 5,711,705).

Hornby in view of McVey is relied upon as set forth in reference to claim 6. Concerning claims 7 and 10, While Hornby discloses an outlet from the plenum chamber, Hornby in view of McVey does not appear to disclose that the outlet from the plenum chamber contains an exhaust filter though which air/sterilant vapour is drawn from the chamber. Krainiak discloses an enclosure for carrying out an operation under sterile conditions comprising a plenum chamber, a filter separating the plenum chamber from the main chamber, a pump for the plenum chamber for delivering air into the plenum chamber and then through the filter to the main chamber to create a filtered flow of air through the chamber and means for drawing gas from the enclosure via an outlet from the main chamber to create a flow of sterilant vapour from the main chamber through the filter decontaminating the filter and through the plenum chamber (Figure 3, columns 3 and 4). The reference continues to disclose an outlet that comprises an exhaust filter (34) in order to remove particulates from the pathway to the atmosphere (column 4, lines 5-8; column 4, lines 35-45). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Hornby to include an exhaust filter in the outlet conduit though which air/sterilant vapour is drawn from the chamber in

order to remove particulates from the pathway to the atmosphere as exemplified by Krainiak. Regarding claim 11, The Manual of Patent Examining Procedures discloses that in *In re Harza,* 274, F.2d 669, 124 USPQ 378 (CCPA 1960), a mere duplication of parts for a multiplied effect has no patentable significance unless a new and unexpected result is produced (See MPEP 2144.04). Accordingly, the addition of two spaced filters in the outlet is considered to be not patentably distinct from the disclosed references.

6. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hornby (U.S. Patent No. 5,906,794) in view of McVey et al. (U.S. Publication No. 2004/0184950) as applied to claim 1 above, and further in view of Morrow et al. (U.S. Patent No. 2002/0168305).

Hornby is relied upon as set forth in reference to claim 1. Hornby does not appear to disclose that the enclosure contains a second apparatus comprising a housing containing a catalytic converter for converting the sterilant into harmless byproducts for disposal and means for circulating the atmosphere of the chamber through the housing to reduce the sterilant concentration in the atmosphere when the sterilization operation has been performed. Morrow discloses an apparatus for use in an enclosure that is capable of rendering sterilant in the atmosphere in a chamber ineffective (paragraphs 2 and 46-49). The reference continues to disclose that the means contains a housing (12) containing a catalytic converter (paragraph 57) capable of converting the sterilant into harmless byproducts for disposal and means (20) for circulating the atmosphere of the chamber through the housing capable of reducing a sterilant concentration in the atmosphere when a sterilization operation has been

performed. The second apparatus is utilized to provide an airstream free from contamination and other elements harmful to people. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Hornby to include a second apparatus comprising a housing containing a catalytic converter capable of converting the sterilant into harmless byproducts for disposal and means for circulating the atmosphere of the chamber through the housing capable of reducing a sterilant concentration in the atmosphere when a sterilization operation has been performed in order to provide an airstream free from contamination and other elements harmful to people as exemplified by Morrow.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin C. Joyner whose telephone number is (571) 272-2709. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCJ

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER